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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/450,880	11/29/1999	DOUGLAS A. CRAIG	56376/JPW/AD	8284

7590 12/21/2001

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EXAMINER	
LU, FRANK WEI MIN	
ART UNIT	PAPER NUMBER
1655	4

DATE MAILED: 12/21/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/450,880	CRAIG, DOUGLAS A.	
	Examiner	Art Unit	
	Frank W Lu	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Location of Application

1. The Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1655.

Response to Amendment

2. Applicant's response to the office action filed on October 15, 2001 has been entered as Paper No: 3. The claims pending in this application are claims 1-24. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn.

Information Disclosure Statement

3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating murine urinary incontinence with compound 1 or compound 2 which activates the human 5-HT_{1F} receptor in an *in vitro* experiment (for the name of compounds, see page 17 of the specification), does not reasonably provide enablement for: (1) treating any kind of subject suffering from urinary incontinence by administering a therapeutically effective amount of a 5-HT_{1F} receptor agonist which activates the human 5-HT_{1F} receptor; (2) treating any kind of subject suffering from urinary incontinence by administering a therapeutically effective amount of a 5-HT_{1F} receptor agonist which activates the human 5-HT_{1F} receptor and can treat one subject suffering from urinary incontinence; and (3) binding of any kind of 5-HT_{1F} receptor agonist that can treat one subject suffering from urinary incontinence to all receptors as recited in claims 1-24 so that all these receptors can be activated. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In *In re Wands*, 858 F.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court considered the issue of enablement in molecular biology. The Court summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the

breadth of the claims. The Court also stated that although the level of skill in molecular biology is high, results of experiments in molecular biology are unpredictable.

To begin, there is no direction or guidance in the specification to show that: (1) any kind of subject suffering from urinary incontinence can be treated with a 5-HT_{1F} receptor agonist which activates the human 5-HT_{1F} receptor; (2) a 5-HT_{1F} receptor agonist that can treat murine urinary incontinence can also work in any kind of subject suffering from urinary incontinence such as human; and (3) any kind of 5-HT_{1F} receptor agonist that can treat one subject suffering from urinary incontinence can bind to all receptor as recited in claims 1-24 so that all these receptors can be activated. While the relative skill in the art is very high (the Ph.D. degree with laboratory experience), there is no predictability whether: (1) any kind of subject suffering from urinary incontinence can be treated with a 5-HT_{1F} receptor agonist which activates the human 5-HT_{1F} receptor and a 5-HT_{1F} receptor agonist that could treat one subject suffering from urinary incontinence can work in any kind of subject since different subjects may have different response to a 5-HT_{1F} receptor agonist; and (2) any kind of 5-HT_{1F} receptor agonist that can treat one subject suffering from urinary incontinence can bind to all receptors as recited in claims 1-24 so that all these receptors can be activated since some of 5-HT_{1F} receptor agonist may not bind to some receptors as recited in claims 1-24.

The invention relates to a method of treating urinary incontinence in a subject which comprises administering to any kind of subject a therapeutically effective amount of a 5-HT_{1F} receptor agonist which activates the human 5-HT_{1F} receptor. The specification (see pages 22-24) only show that, in *a in vitro* experiment, murine urinary incontinence can be treated with

compound 1 or compound 2 (for the name of compounds, see page 17 of the specification). During the prior art search, the examiner could not found that: (1) any kind of subject suffering from urinary incontinence could be treated with a 5-HT_{1F} receptor agonist which activates the human 5-HT_{1F} receptor; (2) a 5-HT_{1F} receptor agonist that could treat murine urinary incontinence can also work in any kind of subject suffering from urinary incontinence such as human; and (3) any kind of 5-HT_{1F} receptor agonist that could treat one subject suffering from urinary incontinence can bind to all receptors as recited in claims 1-24 so that all these receptors can be activated. Accordingly, it is concluded that undue experimentation is required to make the invention as it is claimed. See M.P.E.P.*§§* 706.03(n) and 706.03(z).

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. No claim is allowed.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
December 20, 2001

ETHAN C. WHISENANT
PRIMARY EXAMINER